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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------|------------------|
| 09/647,599 | 10/03/2000 | Leigh T Canham | 124-796 | 1219 |
| 23117 | 7590 | 11/23/2005 | EXAMINER | |
| NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203 | | | KISHORE, GOLLAMUDI S | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1615 | |

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/647,599

Applicant(s)

CANHAM ET AL.

Examiner

Gollamudi S. Kishore, Ph.D

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 167-176 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 167-176 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The RCE dated 9-12-05 is acknowledged.

Claims included in the prosecution are 167-176.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 167-176 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant drafts new claims introducing the limitation that the resorbable mesoporous silicon is hydrophobic. The term, 'hydrophobic' or the stipulation that the silicon has to be hydrophobic does not appear to have support in the specification as originally filed and therefore, deemed to be new matter.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 167-176 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Instant claims are drawn to 'a method of therapeutic or prophylactic treatment'; it is unclear as to what disease or condition the treatment is for.

It is unclear as to what applicant is intending to convey by 'the drug is at least partly located in the silicon skeleton in which the pores are formed as recited in claim 169. According to the parent claim 167, the drug is located at least partly in the pores of the porous silicon. Does the limitation in claim 169 mean that the drug is outside the pores?

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 167-176 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/06101 of record by itself or in combination with Bruinsma (5,922,299) or Wei (6,696,258) both are also of record.

WO discloses biomaterial wherein the bioactive porous silicon is impregnated with active agents such as calcium, sodium or phosphorous. The implant device may be a sensor device or a device for intelligent drug delivery (abstract, page 6, lines 5-6). The porosity is taught on page 13, lines 10-29. Although the porous silicon impregnated with calcium, sodium or phosphorous used in the examples, WO on page 3, lines 23-29 teaches that bioactive silicon could be either microporous (pore diameter 20 Å) or mesoporous (pore diameter 20 Å to 500 Å).

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Therefore, it would have been obvious to one of ordinary skill in the art to use the desired silicon implant, such as mesoporous silicon with the desired pore sizes from the teachings and guidance provided by WO for the delivery of drugs with a reasonable expectation of success. One of ordinary skill in the art would be motivated further to use mesoporous silicon instead of microporous silicon for drug delivery since the references of Bruinsma, and Wei teach that mesoporous silica in particular, have applications in drug delivery (abstract and col. 1, lines 24-29 of Bruinsma and abstract and col. 15, lines 53-56).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that WO does not describe a drug that is located in the pores of hydrophobic silicon. This argument is not found to be persuasive since WO teaches that the porous silicon is impregnated and therefore, active agent in the pores is implicit. Applicant argues that WO describes the erosion of mesoporous silicon, which involves wetting of silicon and point out to pages 12 and 13. This argument is not found to be persuasive since even in instant case, the silicon erodes over an interval of between one month and two years (see claim 173) and a careful review of instant specification on page 9 indicates that the erosion is when tested with SBF (simulated body fluid) just as in the prior art. Applicant argues that WO teaches that porous silicon is oxidized on page 9 lines 13-17. This argument is not found to be persuasive since at this location WO teaches that the porous wafers were stored in ambient air, but it does not state that the wafers are oxidized. Furthermore, it would appear that it is one of the embodiments and not the only embodiment. Even assuming that WO teaches only

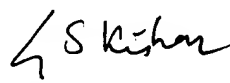
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hydrophilic silicon, the examiner points out that the secondary references teach mesoporous silicon which is not hydrophilic.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK